Falling on deaf ears

People are suffering and dying in their thousands from medicines' side effects. Patients and families complain, but is anyone listening, asks **Millie Kieve**

EVERY day I read emails sent to APRIL, the charity I founded after the death of my daughter Karen. Many people write of their suspicions that the abrupt onset of what had been labelled a psychiatric illness of a family member or friend was in fact caused by a reaction to prescribed medicines or anaesthetics. In some cases, like Karen's, the result can be fatal.

The same suspects turn up time and again: corticosteroids, anti-malarial drugs, acne drugs, tranquillisers and antidepressants among others, prescribed for everything from support for giving up smoking to urinary incontinence.

There is reason to be suspicious. When drugs are subjected to clinical trials, not all the findings are disclosed. And because trials are relatively small and short, rarer side effects – and certainly withdrawal effects – go unrecorded. It is only when a drug is licensed and given to millions that the scale of potential harm can be measured, as with the Cox-2 inhibitor rofecoxib, the painkiller better known as Vioxx, withdrawn in 2004.

I often reply to these emails with data for the patients to show their doctors. This information may come from drug alert warnings issued by authorities in the UK, US or Canada, or from case studies or manufacturers' product information. Occasionally people write back saying their treatment was changed as a result. Sometimes coroners ask me for information about medicines linked to a sudden death, including suspected suicide. One expressed concern about deaths in prison possibly being linked to drugs used for detoxification.

Sadly, my efforts are small in the face of a large problem. Just how large was discovered by Munir Pirmohamed of the University of Liverpool, UK, in 2004, when his team showed that of 18,820 emergency hospital admissions 1225 (6.5 per cent) were due to adverse drug reactions (ADRs). He estimated that 10,000 deaths in UK hospitals were attributable to ADRs, of which some 70 per cent were preventable.

Two years later, the British Medical Association extrapolated from Pirmohamed's research to show that the figures may be higher. It estimates that 250,000 people a year are admitted to UK hospitals suffering harmful effects from prescription drugs, at a cost to the National Health Service of £466 million.

So why is patient safety doing so badly? First, it's no secret that the UK government has a compromised relationship with the pharmaceutical industry and lacks effective ways to obtain adverse data from clinical trials. Investigations by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) into possible criminal offences by pharmaceutical companies have been dragging on for years.

An inquiry by the House of Commons Health Committee into the influence of the pharmaceutical industry found that the MHRA has a conflict of interest in its remit to promote the pharmaceutical industry and to regulate the safety of medicines.

"Too many health professionals are unaware of the system designed to signal adverse drug reactions"

The committee heard many submissions, including that of a consultant cardiologist who said he had been offered the equivalent of two years' salary if he agreed not to disclose scientific data showing a drug in a poor light. And they were told that even when ADRs emerge, manufacturers are slow to or fail to change labels on drug packs and leaflets inside them.

Another major concern is how little doctors know about how medicines are mobilised, metabolised and interact, and of the crucial differences between individuals – related to genetics, race, sex, age and background health. Pharmacology, therapeutics and pharmacogenetics are rarely taught in modules and seminars at most UK medical schools.

Even if doctors spot a serious ADR, fewer than 10 per cent are reported. Too many medical professionals are unaware of the UK's Yellow Card ADR system, which is supposed to signal emerging problems. APRIL's own recent survey of just one hospital shift found more than 50 per cent of doctors and more than 90 per cent of nurses had never heard of it. How many patients know they too can use the system by sending in cards themselves?

There is a glimmer of hope. Parents and siblings of young people who became aggressive or died by suicide after taking antidepressants spoke at a US Food and Drug Administration hearing in Washington DC in February 2004. Their evidence and the re-evaluation of clinical trial data for young people helped to win "black box" warning labels on the packaging of more than 30 antidepressants.

The need for real reform is urgent at a time when fast-track licensing of medicines is being encouraged and investigations into pharmaceutical companies for possible criminal acts drag on. To avoid thousands more casualties, we must campaign for ADR reporting to be made independent and legally enforceable, and for those professionals with prescribing rights to be educated to recognise the warning signs and avoid causing harm.

Millie Kieve is the founder of the UK-based charity APRIL, Adverse Psychiatric Reactions Information Link, which advises on reactions to prescribed medicines